INSTRUCTION SHEET

COMAR 26.12.01.01

Title: Regulations for the Control of Ionizing Radiation (1994)

SUPPLEMENT No. 24

Instructions: Supplement 24 to the document "Regulations for the Control of Ionizing Radiation (1994)" includes the following pages (all pages are inclusive):

Remove Pages	Insert Pages (future)
Cover Sheet	Cover Sheet
B5 through B6	B5 through B6 (4 pages)
C13 through C13-1	C13 through C13-1
C47 through C48	C47 through C48
C51 through C51-1	C51 through C51-1
C53-4 through C58	C53-4 through C58
D37 through D38	D37 through D38
E3 through E8	E3 through E8
F9-2 through F9-3	F9-2 through F9-3
F11 through F12	F11 through F12
F14-1 through F14-2	F14-1 through F14-2
F31-2 through F34	F31-2 through F34
F51 through F52	F51 through F51-4 through F52 (6 pages)
G21 through G22	G21 through G22
T35 through T36	T35 through T36

Verify to make certain that you have the pages listed above.

INQUIRIES TO: Michael Kurman
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Code of Maryland Regulations 26.12.01.01

Adopted: September 9, 1995
Effective: October 9, 1995

Supplement 1	Effective: December 16, 1996
Supplement 2	Effective: November 3, 1997
Supplement 3	Effective: June 29, 1998
Supplement 4	Effective: December 28, 1998
Supplement 5	Effective: June 14, 1999
Supplement 6	Effective: February 7, 2000
Supplement 7	Effective: April 1, 2002
Supplement 8	Effective: October 13, 2003
Supplement 9	Effective: October 27, 2003
Supplement 10	Effective: March 29, 2004
Supplement 11	Effective: June 7, 2004
Supplement 12	Effective: June 20, 2005
Supplement 13	Effective: December 8, 2005
Supplement 14	Effective: October 9, 2006
Supplement 15	Effective: December 17, 2007
Supplement 16	Effective: June 15, 2009
Supplement 17	Effective: June 15, 2009
Supplement 18	Effective: November 15, 2010
Supplement 19	Effective: November 15, 2010
Supplement 20	Effective: September 19, 2011
Supplement 21	Effective: August 6, 2012
Supplement 22	Effective: October 29, 2012
Supplement 23	Effective: January 6, 2014
Supplement 24	Effective: September 15, 2014

REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)

RADIOLOGICAL HEALTH PROGRAM
AIR AND RADIATION MANAGEMENT ADMINISTRATION
MARYLAND DEPARTMENT OF THE ENVIRONMENT
1800 WASHINGTON BOULEVARD
BALTIMORE, MARYLAND 21230

(b) Complete application forms for registration furnished by the Agency that contain all the information required by the forms and accompanying instructions;

(c) Designate on the application form the individual to be responsible for radiation protection.

(d) Include full payment of all fees in the application for registration, as specified in COMAR 26.12.03 for the type(s) of radiation machine(s).

(e) Prohibit any person from furnishing radiation machine servicing or services as described in B.6(d) to a radiation machine facility until such person provides evidence to the registrant that they are currently registered with the Agency as a service provider in accordance with B.6.

(f) Apply for certification of the radiation machine(s) to be located in such facility if the radiation machines will be classified in Groups 1, 2, 3, 4, or 5, as described in COMAR 26.12.02.02B. Application for certification of radiation machines shall be made in accordance with COMAR 26.12.02.02D(2).

Sec. B.6 Application for Registration of Servicing and Services.

(a) Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall apply for registration of such services with the Agency prior to furnishing or offering to furnish any such services.

(b) Application for registration shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions.

(c) Each person applying for registration under this part shall specify:

(1) A knowledge and understanding of the requirements of these regulations;

(2) A list of services to be provided under the registration;

(3) The training and experience needed to perform the services;

(4) The type of measurement instrument(s) to be used, frequency of calibration, and source of calibration; and

(5) The type of personnel dosimeters used, frequency of reading, and replacement or exchange schedule for the exposure monitoring required in B.6(g).

(d) For the purposes of B.6, services may include but shall not be limited to:

(1) Installation and/or servicing of radiation machines and associated radiation machine components,

(2) Calibration of radiation machines or radiation measurement instruments or devices,

(3) Radiation protection or health physics consultations or surveys, and

(4) Personnel dosimetry services.

(e) In performance of radiation machine preventive maintenance services, each registered service provider shall provide the radiation machine facility with a complete preventive maintenance report for each radiation machine for which preventive maintenance has been provided.

(1) Each Preventive Maintenance Report shall be completed on the specific preventive maintenance form made available by the Agency applicable to the type of machine tested. One form is required for each machine for which preventive maintenance has been performed. Each form shall be signed and dated by both the registrant and the service provider.

(2) If the Agency has not published a specific Preventive Maintenance Report form for the type of radiation machine tested, a registered service provider shall use its own preventive maintenance report format containing at minimum the following information:

(i) Signature and date of signature of both registered service provider and authorized facility representative;

(ii) Registered service provider's name and registration number;

(iii) Facility name and facility registration number;

(iv) Tested machine's MDE Machine Number if available and tube serial number;

(v) Room number or room name in which tested machine is located;

(vi) Date of preventive maintenance service;

(vii) Written values of every test taken and measurement made including average value as required, and results of all tests and measurements performed. If calibrations or adjustments are made, the report must include the values measured before and after any calibration or adjustment. Tests performed must comprise at minimum every maintenance service or calibration recommended by the machine's manufacturer; and

(viii) Written documentation that machine passes or fails preventive maintenance tests.

(f) The documentation listed in subsection (e) above shall be provided to the facility within one week after completion of the preventive maintenance service. If preventive maintenance includes installation, assembly, disablement, or disposal of a radiation machine, the 15 day Agency notification requirement in Section B.12(a) shall apply.

(g) Each person registered by the Agency to provide services to radiation machine facilities including installation, assembly, calibration, repair, maintenance, disablement, or removal of radiation machines shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part D of this regulation.

(1) Such monitoring of exposures must be performed during all work with or involving radiation machines by means of each service provider and the provider's employees wearing individual monitoring devices to include at minimum film badges.

(2) Film badge reports shall be reviewed by each registered service provider to assure compliance with the occupational dose limits. Such reports shall be required from the film badge supplier on either a monthly or quarterly basis.

(h) No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the Agency.

Sec B.7 Issuance and Posting of Notice of Registration.

(a) Upon a determination that an applicant meets the requirements of the regulations, the Agency shall issue a notice of registration. For a radiation machine facility, this will be issued in the form of a certificate of registration. Each certificate of registration shall be publicly posted by the radiation machine facility.

(b) The Agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, transfer, or servicing of radiation machines as it deems appropriate or necessary.

Sec. B.8 Expiration of Notice of Registration.

Except as provided by B.9(c), each notice of registration shall expire at the end of the specified day in the month and year stated therein.

Sec. B.9 Renewal of Notice of Registration.

(a) The Agency will grant an application for renewal of registration upon receipt of all documentation and fees required by the Agency.

(b) Each application for renewal of registration of a radiation machine facility must be received by the Agency at least 14 days prior to expiration of the facility's existing registration. Such application shall be made in accordance with the provisions of Section B.5. The Agency shall not grant re-registration unless all previously invoiced radiation machine fees are paid in full.

(c) If a registrant has filed a complete application, not less than 14 days prior to the expiration of the existing notice of registration, including payment of all fees and submission of required inspections or certifications with all violations corrected, the existing notice of registration shall not expire until the application status has been determined by the Agency.

Sec. B.10 Report of Changes.

The registrant shall notify the Agency in writing before making any change which would render the information contained in the application for registration and/or the notice of registration no longer accurate. This includes, but is not limited to, requests for registration cancellation, changes of location and ownership, or changes to radiation machines or tubes. The registrant shall notify the Agency of installation, disposal or disablement of radiation machines within 30 days following such action by providing the Agency with a copy of a completed Form MDE RX 24 signed and dated by a State registered service provider.

Sec. B.10A Compliance with Regulations.

All owners, operators, or possessors of a radiation machine(s) shall comply with all applicable requirements of COMAR 26.12.01, .02, and .03. Any Agency Form RX-2 or RX-2a citing a regulation violation(s) which is presented to a radiation machine facility during or following an inspection by an Agency or State-licensed private inspector constitutes a notice to the facility that a violation(s) has been observed by the inspector. An as-found violation(s):

(b) devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta- and/or gamma-emitting material or 10 microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) shall assure that the tests required by C.22(d)(4)(ii) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

(a) in accordance with the instructions provided by the labels, or

(b) by a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities;

(iv) shall maintain records showing compliance with the requirements of C.22(d)(4)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by C.22(d)(4)(ii) shall be maintained for 3 years after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by C.22(d)(4)(ii) shall be maintained for 3 years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by C.22(d)(4)(iii) shall be maintained for a period of 3 years from the date of the recorded event or until the device is transferred or disposed of;

(v) shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 becquerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under Section C or by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the byproduct material in the device or as otherwise approved by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use; must be furnished to the Manager, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230 within 30 days. Under these circumstances, the criteria set out in Section D.1402, “Radiological Criteria for Unrestricted Use”, may be applicable, as determined by the Agency on a case-by-case basis;

(vi) shall not abandon the device containing radioactive material;

(vii) shall transfer or dispose of the device containing radioactive material by transfer to another general licensee as authorized in C.22(d)(4)(x), or to a person authorized to receive the device by a specific license issued under Section C that authorizes waste collection, or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or as otherwise approved under C.22(d)(4)(ix);

(viii) shall within 30 days after the transfer of a device to a specific licensee or export, furnish a report to: Manager, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230. The report shall contain:

(a) the identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number,

(b) the name, address, and license number of the person receiving the device (license number not applicable if exported), and

(c) the date of the transfer;

(ix) shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in C.22(d)(4)(vii); however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

(a) verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(b) removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by (d)(4)(i) of this section) so that the device is labeled in compliance with D.904(a); however, the label must retain the manufacturer, model number, and serial number;

(c) obtains manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak test procedures); and

(d) reports the transfer under (d)(4)(viii) of this section.

(x) shall transfer the device to another general licensee only if:

(a) the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of Sections C.20(a), C.22(d), C.38, D.1201, and D.1202 and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Manager, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230:

(1) the manufacturer's (or initial transferor's) name,

(2) the model number and the serial number of the device transferred,

(3) the transferee's name and mailing address for the location of use, and

(4) the name, title, and phone number of the responsible individual identified by the transferee in accordance with C.22(d)(4)(xii) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

Sec. C.30 Issuance of Specific Licenses.

(a) Upon a determination that an application meets the requirements of the Act and the regulations of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) prevent loss or theft of material subject to this part.

Sec. C.31 Specific Terms and Conditions of Licenses.

(a) Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b) (1) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

(2) An application for transfer of license must include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by Section C.29.

(c) Each person licensed by the Agency pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(d) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(e) Each specific licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) the licensee;

(2) an entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(f) The notification specified in C.31(e) shall indicate the bankruptcy court in which the petition for bankruptcy was filed, a copy of the bankruptcy petition, and the date of the filing of the petition.

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Section G.204. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(h) Production of PET Radioactive Drugs.

(1) Authorization under Section C.26(g) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under Section C.26(g) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in Section C.28(j)(1)(iv) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in Section C.28(j)(3).

(3) A licensee that is a pharmacy authorized under Section C.26(g) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in Section C.28(j)(2), or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in Section G.27.

(4) A pharmacy, authorized under Section C.26(g) to produce PET radioactive drugs for non-commercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirement of Section C.28(j)(2)(v).

(i) As the final step in decommissioning, the licensee shall—

(1) Certify to the Agency in writing the disposition of all licensed material, including accumulated wastes; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406. The licensee shall, as appropriate—

(i) Report levels of gamma radiation in units of millisieverts (microroentgens) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters—removable and fixed—for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instruments(s) used and certify that each instrument is properly calibrated and tested.

(3) Forward all records required by Sec. C.38 to the Agency.

(j) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:

(1) Radioactive material has been properly disposed of;

(2) Reasonable effort (as determined by the Agency) has been made to eliminate residual radioactive contamination if present; and

(3) (i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406.

Sec. C.33 Application for Renewal of Licenses.

(a) Subject to C.32(a), an application for renewal of a specific license must be filed on a form prescribed by the Agency, in accordance with C.24.

(b) All applications for the renewal of a specific license shall be submitted to the Agency for review and approval seven (7) months prior to the expiration date of the license.

Sec. C.34 Amendment of Licenses at Request of Licensee. Applications for amendment of a license shall be filed in accordance with C.24 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Sec. C.35 Agency Action on Applications to Renew or Amend. In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in C.25, C.26, C.27, and C.28 and in Parts E, G, or W of these regulations, as applicable.

Sec. C. 36 Person Possessing a License for Medical Use of Radioactive Material on Effective Date of These Regulations. Any person or institution possessing a specific license for the medical use of radioactive material issued prior to October 9, 1995 when the licensee was authorized according to Groups I through VI of Schedule C, Part C, shall be deemed to possess a license issued under the revised regulations, according to Part G. The existing license will be valid until its stated expiration date and the renewal will be issued in accordance with the regulations dated October 9, 1995.

Sec. C.37 Registration of Sources or Devices Containing Radioactive Materials.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific or general license may submit a request to the Agency for evaluation of radiation safety information about its product and for its registration.

(b) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(c) The Agency normally evaluates a sealed source or device using radiation safety criteria in accordance with accepted industry standards. If these standards and criteria do not readily apply to a particular case, the agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(d) After completion of the evaluation, the Agency may issue a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

(e) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(1) The statements and representation, including quality control program, contained in the request; and

(2) The provisions of the registration certificate.

(f) For sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the Agency under Section C.37, with the NRC under 10 CFR 32.210, or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in Section C.37, the applicant shall provide:

(1) All available information identified in Section C.37 concerning the source, and, if applicable, the device; and

(2) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information shall include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

Sec. C.38 Records.

(a) Each person who receives radioactive material through a license issued pursuant to the regulations in this part shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

(1) The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three years following transfer or disposal of the material.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency order.

Sec. C.51 - C.89 Reserved.

RECIPROCITY

Sec. C.90 Reciprocal Recognition of Licenses.

(a) Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to these regulations, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license within this state, excluding offshore waters and areas of exclusive Federal jurisdiction, for a period not in excess of 180 days in any calendar year to possess radioactive material and/or to conduct the activities authorized in such licensing document provided that:

(i) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) the out-of-state licensee notifies the Agency in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.90(a)(1);

(iii) the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;

(iv) the out-of-state licensee supplies such other information as the Agency may request; and

(v) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.90(a)(1) except by transfer to a person:

(a) specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission to receive such material, or

(b) exempt from the requirements for a license for such material under C.4(a).

(2) Notwithstanding the provisions of C.90(a)(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in C.22(d)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:

(i) such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;

(iii) such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(iv) the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in C.22(d) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an Agreement State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(b) Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material.

(1) Subject to these regulations, any person who holds a specific license from a Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license within this State for a period not in excess of 180 days in any calendar year to possess radioactive material and/or to conduct the activities authorized in such licensing document provided that:

(i) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) the out-of-state licensee notifies the Agency in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.90(b)(1);

(iii) the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;

(iv) the out-of-state licensee supplies such other information as the Agency may request; and

(v) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.90(b)(1) except by transfer to a person:

(a) specifically licensed by the Agency or by another Licensing State to receive such material, or

(b) exempt from the requirements for a license for such material under C.4.

(2) Notwithstanding the provisions of C.90(b)(1), any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in C.22(d)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:

(i) Such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State;

(iii) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement the "Removal of this label is prohibited"; and

(iv) The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in C.22(d) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(c) Reciprocity of Maryland Licensees.

(1) Prior to a State of Maryland company conducting licensed activities in offshore waters or areas of exclusive Federal jurisdiction that company shall meet all pertinent requirements of 10 CFR 150.20.

(2) Any person engaging in activities in non-Agreement States, in areas of exclusive Federal jurisdiction within Agreement States, or in offshore waters under the general licenses provided in 10 CFR 150.20, shall not, in any non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters, transfer or dispose of radioactive material possessed or used under the general licenses provided in 10 CFR 150.20, except by transfer to a person who is specifically licensed by the NRC to receive this material.

(3) Any person who holds a specific license issued by the Agency authorizing the holder to manufacture, install, or service a device described in Section C.22(d) of this regulation within Maryland is hereby granted a general license to install and service such device in any non-Agreement State and a general license to install and service such device in offshore waters, as defined in 10 CFR 150.3(f), provided that:

(i) [Reserved]

(ii) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Agency.

(iii) Such person assures that any labels required to be affixed to the device under Maryland regulations which licensed manufacture of the device bear a statement that removal of the label is prohibited.

Part C

APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Antimony (51)	Sb-122		$3X10^{-4}$
	Sb-124		$2X10^{-4}$
	Sb-125		$1X10^{-3}$
Argon (18)	Ar-37	$1X10^{-3}$	
	Ar-41	$4X10^{-7}$	
Arsenic (33)	As-73		$5X10^{-3}$
	As-74		$5X10^{-4}$
	As-76		$2X10^{-4}$
	As-77		$8X10^{-4}$
Barium (56)	Ba-131		$2X10^{-3}$
	Ba-140		$3X10^{-4}$
Beryllium (4)	Be-7		$2X10^{-2}$
Bismuth (83)	Bi-206		$4X10^{-4}$
Bromine (35)	Br-82	$4X10^{-7}$	$3X10^{-3}$
Cadmium (48)	Cd-109		$2X10^{-3}$
	Cd-115m		$3X10^{-4}$
	Cd-115		$3X10^{-4}$
Calcium (20)	Ca-45		$9X10^{-5}$
	Ca-47		$5X10^{-4}$
Carbon (6)	C-14	$1X10^{-6}$	$8X10^{-3}$
Cerium (58)	Ce-141		$9X10^{-4}$
	Ce-143		$4X10^{-4}$
	Ce-144		$1X10^{-4}$
Cesium (55)	Cs-131		$2X10^{-2}$
	Cs-134m		$6X10^{-2}$
	Cs-134		$9X10^{-5}$
Chlorine (17)	Cl-38	$9X10^{-7}$	$4X10^{-3}$
Chromium (24)	Cr-51		$2X10^{-2}$
Cobalt (27)	Co-57		$5X10^{-3}$
	Co-58		$1X10^{-3}$
	Co-60		$5X10^{-4}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ μCi/g for solids.

i. An individual to receive, in a period of 24 hours:

(1) A total effective dose equivalent exceeding 0.05 Sv (5 rem); or

(2) A lens dose equivalent exceeding 0.15 Sv (15 rem); or

(3) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

ii. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

c. The licensee or registrant shall prepare each report filed with the Agency pursuant to D.1202 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

d. The provisions of D.1202 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to D.206a and D.1204.

Sec. D.1203 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

a. Reportable Events. In addition to the notification required by D.1202, each licensee or registrant shall submit a written report to the Agency within 30 days after learning of any of the following occurrences:

i. Incidents for which notification is required by D.1202; or

ii. Doses in excess of any of the following:

(1) The occupational dose limits for adults in D.201; or

(2) The occupational dose limits for a minor in D.207; or

(3) The limits for an embryo/fetus of a declared pregnant woman in D.208; or

(4) The limits for an individual member of the public in D.301; or

(5) Any applicable limit in the license or registration; or

(6) The ALARA constraints for air emissions established under D.101(d); or

iii. Levels of radiation or concentrations of radioactive material in a restricted or unrestricted area in excess of the applicable limits set forth in any license or registration condition.

b. Contents of Reports.

i. Each report required by D.1203a. shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(1) Estimates of each individual's dose; and

(2) The levels of radiation and concentrations of radioactive material involved; and

(3) The cause of the elevated exposures, dose rates, or concentrations; and

(4) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

ii. Each report filed pursuant to D.1203a. shall include for each individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in D.208, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

Sec. D.1204 Reports of Planned Special Exposures.

The licensee or registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with D.206, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Sec. D.1106.

Sec D.1205 Reports to Individuals of Exceeding Dose Limits.

When a licensee or registrant is required pursuant to D.1203 to report to the Agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide a copy of the report submitted to the Agency to the individual. This report shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of J.13a. of these regulations.

Sec. D.1206 Reports of Leaking or Contaminated Sealed Sources.

If the test for leakage or contamination required pursuant to D.401 indicates a sealed source is leaking or contaminated, a written report of the test shall be filed within 5 days with the Agency describing the equipment involved, the test results and the corrective action taken.

"Practical Examination" means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

"Radiation Safety Officer (RSO)" for industrial radiography means an individual with the responsibility for the overall radiation safety program on behalf of the licensee and who meets the requirements of Sec. E.42.

"Radiographer" means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Department's regulations and the conditions of the license.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

"Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses a radiation machine, radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in industrial radiography.

"Radiographic exposure device (also called a camera, or a projector)" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

"Radiographic operations" means all activities associated with the use of a radiation machine, or with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

"Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

"Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

"Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

"Storage area" means any location, facility, or vehicle which is used to store or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

"Storage container" means a container in which sealed sources are secured and stored.

"Underwater radiography" means industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

Subpart B - Exemptions and Cabinet Radiography

Sec. E.4 Exemptions.

(a) Except for the requirements of E.5, certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this part.

(b) Industrial uses of lixiscopes are exempt from the requirements of this part.

Sec. E.5 Special Requirements for Cabinet Radiography.

(a) Systems for cabinet radiography designed to allow admittance of individuals shall:

(1) Comply with all applicable requirements of this part and D.301 of these regulations. If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this part and 21 CFR 1020.40.

(2) Be evaluated at intervals not to exceed 1 year to assure compliance with the applicable requirements of Part E. Records of these evaluations shall be maintained for inspection by the Agency for a period of 3 years after the evaluation.

(b) Certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this part except that:

(1) Operating personnel must be provided with and required to wear either film badges or thermoluminescent dosimeters, and reports of the results of such monitoring shall be maintained for inspection by the Agency.

(2) No registrant shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by the Agency until disposition is authorized by the Agency.

(3) The registrant shall perform an evaluation, at intervals not to exceed 1 year, to determine conformance with D.301 of these regulations. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed 1 year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the Agency for a period of 3 years after the evaluation.

(c) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Agency pursuant to Part A.3(a) of these regulations.

Subpart C - Equipment

Sec. E.20 Performance Requirements for Industrial Radiography Equipment Using Sealed Sources of Radiation.

Equipment used in industrial radiographic operations must meet the following minimum criteria:

(a) (1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standards Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (published as NBS Handbook 136, issued January 1981). This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036; Telephone: (212) 642-4900.

(2) Notwithstanding the provisions of paragraph E.308(a)(1), engineering analyses may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography components. Upon review, the Agency may find this an acceptable alternative to actual testing of the component pursuant to the referenced standard.

(b) In addition to the requirements specified in paragraph (a) of this section, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:

(1) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the--

(i) Chemical symbol and mass number of the radionuclide in the device;

(ii) Activity and the date on which this activity was last measured;

(iii) Model (or product code) and serial number of the sealed source;

(iv) Manufacturer's identity of the sealed source; and

(v) Licensee's name, address, and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR Part 71.

(3) Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(c) In addition to the requirements specified in paragraphs (a) and (b) of this section, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers:

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(4) (i) Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER--RADIOACTIVE."

(ii) The label may not interfere with the safe operation of the exposure device or associated equipment.

(5) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

(6) Guide tubes must be used when moving the source out of the device.

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

(9) Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this section.

(e) Notwithstanding paragraph (a)(1) of this section, equipment used in industrial radiographic operations need not comply with Sec. 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

Sec. E.21 Limits on External Radiation Levels from Storage Containers and Source Changers.

The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 millirem) per hour at any exterior surface, and 0.1 millisieverts (10 millirem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

Sec. E.23 Locking of Radiation Machines, Radiographic Exposure Devices, Storage Containers and Source Changers.

(a) Each radiation machine and radiographic exposure device must have a lock to prevent unauthorized use, or have an outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The radiation machine or exposure device and/or its container must be kept locked (and if a keyed-lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in Sec. E.51. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

(b) Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (and if a keyed-lock, with the key removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

Sec. E.25 Radiation Survey Instruments.

(a) The licensee shall keep sufficient calibrated and operable radiation survey instruments at each location where a radiation machine or radioactive material is present to make the radiation surveys required by this part and by Part D of this regulation. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 millirems) per hour through 0.01 sievert (1 rem) per hour.

(b) The licensee shall have each radiation survey instrument required under paragraph (a) of this section calibrated--

(1) At intervals not to exceed 3 months and after instrument servicing, except for battery changes;

(2) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 millirems) per hour; and

(3) So that an accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked.

(c) The licensee shall maintain records of the results of the instrument calibrations in accordance with Sec. E.65.

Sec. E.27 Leak Testing and Replacement of Sealed Sources.

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the Agency, the NRC or an Agreement State.

(b) The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Agency, the NRC or an Agreement State.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

“Thyroid shielding” means a collar or shield consisting of ≥0.5 mm lead equivalent which is effective in protecting a patient’s thyroid gland from direct exposure to the useful x-ray beam.

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

"X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

(2) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

(3) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location, and includes x-ray equipment permanently installed in a vehicle.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate, or AKR, is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray subsystem" means any combination of two or more components of an x-ray system.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray tube" means any electron tube which is designed to be used primarily for the production of x rays.

(v) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(a) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by no less than 0.5 millimeter lead equivalent.

(b) All persons shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

(c) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(vi) Gonad shielding of not less than 0.5 millimeter lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(vii) Thyroid shielding consisting of a $\geq$0.5 mm lead equivalent thyroid collar or shield shall be provided to and used for all patients upon request or whenever the useful beam is expected to or may strike the thyroid gland, so long as such shielding does not interfere with diagnostic x-ray procedures.

(viii) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision also prohibits deliberate exposure for the purpose of training, demonstration, or other non-healing-arts purposes.

(ix) When a patient or film must be provided with auxiliary support during a radiation exposure:

(a) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by Section F.3(a)(1)(iv), shall list individual projections where holding devices cannot be utilized;

(b) Written safety procedures, as required by Section F.3(a)(l)(iv), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(c) The human holder shall be protected as required by Section F.3(a)(1)(v);

(d) No individual shall be used routinely to hold film or patients; and

(e) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

(f) The beam defining light, if present, shall be turned on during all exposures for which a human holder is used. The operator shall not initiate the exposure except on permission from the holder.

(g) No individual who is occupationally exposed to radiation shall be required to hold patients during radiographic exposures.

(x) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. Such procedures and equipment shall include, but are not limited to the following requirements:

(a) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations;

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality;

(c) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation; or

(d) X-ray systems subject to Section F.6 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

(e) Filmless diagnostic x-ray systems shall use technique factors not to exceed the maximum of the technique range recommended by manufacturers' specifications to generate images.

(xi) All individuals who are associated with the operation of an x-ray system are subject to the requirements of Part D of these regulations. In addition:

(a) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

(1) When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.

(2) Manual Processing of Film.

(i) Where film is developed manually, a system shall be available which consists of at least one three-sectional tank made of mechanically rigid, corrosion resistant material (each section of which shall be constructed so as to retain its solution separate from the other two) and has the overall temperature controlling capability of maintaining each solution such that the temperature of each solution will always fall within the range of 60°F to 80°F (16-27°C).

(ii) Devices shall be available which will:

(a) Give the actual temperature of the developer, plus or minus 2°F (or 1°C if SI units are used),

(b) Give an audible or visible signal after a preset time, plus or minus 10% of the preset time, and

(iii) Film shall be developed in accordance with the appropriate time and temperature charts. Time and temperature charts matched to the film types in use in the facility shall be available and posted in the development work area.

(3) Chemical-Film Processing Control.

(i) Chemicals shall be mixed in accordance with the chemical manufacturer's recommendations.

(ii) Replenishing of chemicals shall be sufficient to maintain the standards of Section F.3(b)(1) above.

(iii) All processing chemicals shall be completely replaced at least every 3 months.

(4) Automatic Processors and Other Closed Processing Systems. Preventive maintenance shall be performed on the unit, except for extended periods of non-use, on a frequency basis which is not less than that schedule recommended by the manufacturer. In the event that no schedule is available from the manufacturer, a maintenance schedule shall be established which will preserve good film quality.

(5) Film Fog Prevention.

(i) Film processing areas and devices shall be constructed so that film being processed, handled, or stored will be exposed only to light which has passed through a proper safelight filter.

(ii) That light which remains in a film processing area or device following compliance with F.3(b)(5)(i) shall, when exposed to film in a two minute fog test, produce an increase in fog of not more than 0.05 density units.

(iii) In determining compliance with F.3(b)(5)(ii), fog measurements are to be made at exposed film densities of 1.0 plus base plus fog.

(6) Soft Copy Image Production.

(i) Display monitors. The registrant shall use only appropriate display monitors that meet the manufacturer's recommended specifications for diagnostic interpretation for image quality parameters.

(ii) Lasers. The registrant shall use only appropriate lasers that meet the manufacturer's recommended specifications for image quality parameters.

(iii) Replacement devices for electronic image retrieval or duplication instrumentation shall meet manufacturers' recommended specifications.

(c) Quality Assurance.

The registrant shall be responsible for establishing and operating an effective program for radiographic or fluoroscopic imaging quality control. This program shall be designed to fulfill the following goals:

(1) That the diagnostic quality of radiographic or fluoroscopic images will be maintained at the highest level;

(2) That film processing systems, including electronic imaging collection systems, will be maintained at the highest quality level;

(3) That radiographic or fluoroscopic images will be produced using the minimum radiation doses to patients; and

(4) That the above three goals will be consistently met.

(d) Machine Maintenance.

(1) A registrant shall maintain each radiation machine in accordance with the manufacturer's recommended maintenance specifications.

(2) If documentation regarding the recommended maintenance schedule is not available from the manufacturer, maintenance shall be performed at intervals not to exceed 12 months.

(3) A registrant shall maintain documentation that the machine manufacturer's recommended maintenance schedule has been met. Documentation to satisfy the requirements of this section shall include a detailed service report that includes the results of all tests performed by the registered service company. Such documentation shall clearly designate the registrant name and facility registration number, service date and provider of maintenance service, Department-assigned machine number, if present, and tube serial number, and room name or number in which the machine is located, for each machine for which preventive maintenance has been provided.

(4) Each registrant shall provide to the Agency written documentation as described in (d)(3) sufficient to demonstrate that the maintenance required under (d)(1) and (2) has been performed. Such documentation shall be provided to the Agency no later than thirty (30) days following performance of this maintenance.

(j) Requirements for Patient Safety.

Thyroid shielding consisting of a ≥0.5 mm lead equivalent thyroid collar or shield shall be provided to and used for all patients, so long as such shielding does not interfere with diagnostic x-ray procedures.

Therapeutic X-Ray Systems

Sec. F.8 Therapeutic X-Ray Systems of Less Than One MeV.

(a) Equipment Requirements.

(1) Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that x-ray system.

(i) Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 μC/kg) per hour at 5 centimeters from the surface of the tube housing assembly.

(ii) 0-150 kVp Systems. Systems which were manufactured or installed prior to December 6, l982 shall have a leakage radiation which does not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source.

(iii) 0-150 kVp Systems. Systems which are manufactured on or after December 6, l982 shall have a leakage radiation which does not exceed 100 milliroentgens (25.8 μC/kg) in 1 hour at 1 meter from the source.

(iv) 151 to 999 kVp Systems. The leakage radiation shall not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source not to exceed 0.1 percent of the useful beam 1 meter from the source.

(2) Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

(3) Removable and Adjustable Beam Limiting Devices.

(i) Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

(ii) Adjustable beam limiting devices installed after December 6, l982 shall meet the requirements of F.8(a)(3)(i).

(iii) Adjustable beam limiting devices installed before December 6, l982 shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kilovoltage and maximum treatment filter.

(4) Filter System. The filter system shall be so designed that:

(i) the filters cannot be accidentally displaced at any possible tube orientation;

(ii) the radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under any operating conditions; and

(iii) each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

(5) Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.

(6) Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Beam Monitor System. Systems of greater than 150 kVp manufactured after December 6, l982 shall be provided with a beam monitor system which:

(i) shall have the detector of the monitor system interlocked to prevent incorrect positioning;

(ii) shall not allow irradiation until a pre-selected value of exposure has been made at the treatment control panel;

(iii) shall independently terminate irradiation when the preselected exposure has been reached;

(iv) shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;

(v) shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;

(vi) shall have a control panel display which maintains the administered dose reading until intentionally reset to zero; and

(vii) shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

(9) Timer.

(i) A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.

(ii) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

(iii) The timer shall terminate irradiation when a pre-selected time has elapsed if any dose monitoring system present has not previously terminated irradiation.

(iv) The timer shall permit accurate presetting and determination of exposure times as short as 1 second.

(v) The timer shall not permit an exposure if set at zero.

(vi) The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.

(10) Control Panel Functions. The control panel, in addition to the displays required in other provisions of F.8, shall have:

(i) an indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

(ii) an indication of whether x rays are being produced;

(iii) means for indicating x-ray tube potential and current;

(iv) means for terminating an exposure at any time;

(v) a locking device which will prevent unauthorized use of the x-ray system; and

(vi) for x-ray systems manufactured after December 6, l982, a positive display of specific filter(s) in the beam.

(11) Multiple Tubes. When a control panel may energize more than one x-ray tube:

(i) It shall be possible to activate only one x-ray tube at any time.

(ii) There shall be an indication at the control panel identifying which x-ray tube is energized.

(iii) There shall be an indication at the tube housing assembly when that tube is energized.

(12) Source-to-Skin Distance. There shall be means of determining the SSD to within 1 centimeter.

(13) Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition,

(i) after the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and

(ii) an indication of shutter position shall appear at the control panel.

(14) Low-Filtration X-Ray Tubes. Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

(b) Facility Design Requirements for X-Ray Systems Capable of Operating Above 50 kVp.

(1) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

(2) Viewing Systems.

Other Diagnostic X-Ray Systems

Sec. F.10 Veterinary Medicine Radiographic Installations.

(a) Equipment.

(1) The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 μC/kg), or 0.88 milligray, in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the protective tube housing. Except for certified systems, a method shall be provided to indicate the SID to within 2 inches.

(i) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam, or

(ii) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(4) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Such means shall provide that the resulting time interval, product of current and time, number of pulses or radiation exposure is accurate to within ten percent of the true value.

(i) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(ii) Timer Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed:

$$\overline{T} \geq 5\,(T_{max} - T_{min})$$

(iii) Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\bar{E}$) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$\bar{E} \geq 5 (E_{max} - E_{min})$$

(iv) kVp Accuracy. Except for certified systems, the true value of kVp shall not be different from the indicated value by greater than ten percent.

(5) A dead-man type of exposure switch shall be provided, together with an approved electrical actuator cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83 m) from the animal during all x-ray exposures.

(6) Beam Limitation for Portable or Stationary X-Ray Systems. Beam limitation for portable and stationary veterinary x-ray systems shall meet the beam limitation requirements of F.10(a)(2)(i) and

(i) There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

(iii) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field, and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(iv) A method shall be provided to indicate the SID to within 2 percent of its true value when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(b) Structural Shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with D.201, D.207, and D.301 of these regulations.

(c) Operating Procedures.

(1) Except when using hand-held devices, the operator shall stand well away from the useful beam and the animal during radiographic exposures.

(2) No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

(4) At no time shall minors be used as animal holders for positioning, restraint or assistance during a radiographic or fluoroscopic examination.

(d) Additional Requirements Applicable to Hand-Held Radiographic Devices.

(1) Equipment.

(i) The protective tube housing shall meet the requirements of F.4(c).

(ii) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall meet the requirements of Sections F.6(a)(1)(ii) or F.6(a)(5), and F.6(a)(6), and shall provide the same degree of protection as is required of the protective tube housing.

(iii) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(iv) A device shall be provided to terminate the exposure after a preset time or exposure.

(2) Conditions of Use.

(i) A hand-held radiation machine is allowed in veterinary offices as a replacement for or in addition to the use of a standard radiographic machine, or may be used as a portable veterinary radiation machine in the field at remote locations.

(ii) A device designed to be hand-held may be permanently installed in an appropriate support frame and used as a free-standing portable x-ray machine.

(3) Additional Requirements Applicable to Systems Specifically Designed to be Hand-Held.

(i) Each hand-held diagnostic x-ray device shall be FDA approved and registered with the Agency for hand-held operation as part of the facility registration. Registration shall include a description of how the hand-held device(s) will be secured in accordance with F.10(d)(4)(v).

(ii) Each individual operating a hand-held diagnostic x-ray device shall, before using the device, complete the manufacturer's training for use of the device. The registrant shall maintain training certificates for operators of hand-held devices and make them available for inspection at the registered facility.

(iii) Hand-held diagnostic x-ray devices shall comply with the following requirements:

(a) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

(b) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$|\overline{X}_1 - \overline{X}_2| \leq 0.10\,(\overline{X}_1 + \overline{X}_2),$$

where $\overline{X}_1$ and $\overline{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

(c) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(d) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(e) Beam Quality. All certified hand-held x-ray devices shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of F.4(e)(1).

(4) Hand Held Operating Procedures.

(i) A log of hand-held usage must be maintained on a form provided by the Agency.

(ii) Hand-held radiation machines require film speeds of 400 ASA or faster or with digital imaging.

(iii) Each individual operating a hand-held device must complete the manufacturer's training and submit the training certificate(s) to the Agency. The records will be maintained by the Agency as part of the facility registration.

(iv) When registering the device, the facility must indicate to the Agency that the intended manner of use is hand-held operation.

(v) The device shall be locked up after use and a description of where and how the device will be stored must be provided to the Agency.

(vi) The device must be in lock down (Safety) mode when it is not active so that exposures cannot be taken.

(vii) The device shall have a permanently mounted non-removable shield in order to protect the operator from backscatter radiation.

(viii) Only those persons licensed to operate radiographic equipment in the State of Maryland are permitted to make exposures using this device.

(ix) The operator must wear a whole body dosimeter when taking an exposure.

(x) If the device is missing or stolen, the facility must immediately report such loss or theft to the Agency.

Sec. F.11 Computed Tomography X-Ray Systems.

(a) Definitions. In addition to the definitions provided in A.2 and F.2 of these regulations, the following definitions shall be applicable to F.11:

"Computed tomography dose index" means the integral from -*7*T to +*7*T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = (1/nT) \int_{-7T}^{+7T} D(z)dz$$

where:

z = Position along a line perpendicular to the tomographic plane.
D(z) = Dose at position z.
T = Nominal tomographic section thickness.
n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_w}$$

where:
μ_x = Linear attenuation coefficient of the material of interest.
μ_w = Linear attenuation coefficient of water.
$(CTN)_x$ = CTN of the material of interest.
$(CTN)_w$ = CTN of water.

"CS" (See "Contrast scale")

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in F.2.

"CTDI" (See "Computed tomography dose index")

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (See "CT number")

(d) A licensee shall also perform checks and tests required by G.60.B(b) following adjustment or repair of the dose calibrator.

(e) A licensee shall retain a record of each check and test required by G.60.B(b) for 3 years. The records required by G.60.B(b) shall include:

(1) For G.60.B(b)(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For G.60.B(b)(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the identity of the individual performing the test;

(3) For G.60.B(b)(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test; and

(4) For G.60.B(b)(4), the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the identity of the individual performing the test.

Sec. G.61 Calibration and Check of Survey Instruments.

(a) A licensee shall ensure that the survey instruments used to show compliance with this part have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

(b) To satisfy the requirements of G.61(a), the licensee shall:

(1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(c) To satisfy the requirements of G.61(b), the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(d) A licensee shall check each survey instrument for proper operation with a dedicated check source before each use. The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each calibration required in G.61(a) for 3 years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

(f) To meet the requirements of G.61(a), G.61(b), and G.61(c), the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by G.61(e) shall be maintained by the licensee.

Sec. G.62 Reserved.

Sec. G.63 Determination of Dosages of Unsealed Radioactive Material for Mobile Medical Use.

(a) A licensee shall determine with a dose calibrator and record the activity of each dosage prior to medical use in accordance with G.60.B except where allowed in G.63(b)(2) and G.63(c)(2).

(b) For a unit dosage, this determination must be made by:

(1) Direct measurement of radioactivity; or

(2) For radiopharmaceuticals delivered directly to a hub, after measurement with a dose calibrator at the hub, a decay correction, based on the activity or activity concentration determined by:

(i) A manufacturer or preparer licensed under Sec. C.28, or equivalent NRC or Agreement State requirements; or

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(iii) A PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC regulations.

(c) For other than unit dosages, this determination must be made by:

(1) Direct measurement of radioactivity; or

(2) For radiopharmaceuticals delivered directly to a hub, after measurement with a dose calibrator at the hub, a combination of volumetric measurements and mathematical calculations, based on the direct measurement made by:

(i) A manufacturer or preparer licensed under Sec. C.28 or equivalent Agreement State or NRC requirements; or

(ii) A PET radioactive drug producer licensed under C.26(g) or equivalent Agreement State or NRC requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

Table A-1—A_1 and A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Se-75	Selenium (34)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	3.9	$1.1X10^{2}$
Sm-145	Samarium (62)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.8X10^{1}$	$2.6X10^{3}$
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-1}$	$2.3X10^{-8}$
Sm-151		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.7X10^{-1}$	$2.6X10^{1}$
Sm-153		9.0	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Sn-119m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Sn-121m (a)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	2.0	$5.4X10^{1}$
Sn-123		$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Sn-125		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{3}$	$1.1X10^{5}$
Sn-126 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.8X10^{-2}$
Sr-82 (a)	Strontium (38)	$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.3X10^{3}$	$6.2X10^{4}$
Sr-85		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.8X10^{2}$	$2.4X10^{4}$
Sr-85m		5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.2X10^{6}$	$3.3X10^{7}$
Sr-87m		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$4.8X10^{5}$	$1.3X10^{7}$
Sr-89		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$
Sr-90 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	5.1	$1.4X10^{2}$
Sr-91 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Sr-92 (a)		1.0	$2.7X10^{1}$	$3.0X10^{-1}$	8.1	$4.7X10^{5}$	$1.3X10^{7}$
T(H-3)	Tritium (1)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.6X10^{2}$	$9.7X10^{3}$
Ta-178 (long-lived)	Tantalum (73)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$4.2X10^{6}$	$1.1X10^{8}$
Ta-179		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.1X10^{1}$	$1.1X10^{3}$
Ta-182		$9.0X10^{-1}$	$2.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Tb-157	Terbium (65)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-158		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-160		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$

Table A-1—A_1 and A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Tc-95m ([a])	Technetium (43)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
Tc-96		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.2X10^{4}$	$3.2X10^{5}$
Tc-96m ([a])		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.4X10^{6}$	$3.8X10^{7}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2X10^{-5}$	$1.4X10^{-3}$
Tc-97m		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
Tc-98		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.2X10^{-5}$	$8.7X10^{-4}$
Tc-99		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.3X10^{-4}$	$1.7X10^{-2}$
Tc-99m		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$
Te-121	Tellurium (52)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		5.0	$1.4X10^{2}$	3.0	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		8.0	$2.2X10^{2}$	1.0	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
Te-125m		$2.0X10^{1}$	$5.4X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.7X10^{2}$	$1.8X10^{4}$
Te-127		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.8X10^{4}$	$2.6X10^{6}$
Te-127m ([a])		$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
Te-129		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{5}$	$2.1X10^{7}$
Te-129m ([a])		$8.0X10^{-1}$	$2.2X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Te-131m ([a])		$7.0X10^{-1}$	$1.9X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{4}$	$8.0X10^{5}$
Te-132 ([a])		$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-3}$	$1.4X10^{-1}$	$1.1X10^{3}$	$3.1X10^{4}$
Th-228 ([a])		$5.0X10^{-1}$	$1.4X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.0X10^{1}$	$8.2X10^{2}$
Th-229		5.0	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$
Th-231		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$
Th-234 ([a])		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.6X10^{2}$	$2.3X10^{4}$
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 ([a])	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	6.4	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$